Claims

1. A method of forming a balloon for a medical device, wherein a tubing of a thermoplastic polymer material is radially expanded under a first elevated pressure at an elevated temperature to form the balloon at a first diameter, the thermoplastic polymer material being a block copolymer material and the method including the further step of annealing the balloon at a second elevated temperature and a second pressure less than the first elevated pressure for a time sufficient to shrink the formed balloon to a second diameter less than the first diameter.

2. A method as in claim 1 wherein the temperature, time and pressure of the annealing step are selected so that the diameter at of the balloon at 3 atm pressure is about 90% or less of the 3 atm diameter of a correspondingly prepared balloon prepared without said shrinking step.

3. The method as in claim 1, wherein the second elevated temperature is less than the first elevated temperature.

4. The method as in claim 1, wherein the block copolymer is made up of soft segments of a polyether and hard segments of a polyester or a polyamide.

5. The method as in claim 4, wherein the second pressure is no more than 20 psi.

6. The method as in claim 5, wherein the first elevated temperature is within the range of 90-100°C and the second elevated temperature is within the range of 70-100°C and is less than the first elevated temperature.

7. The method as in claim 4, wherein the polyether soft segments are polyethers of C_2-C_{10} diols.

8. The method as in claim 4, wherein the hard segments are polyesters of an aromatic dicarboxylic acid and a C_2-C_4 diol.

9. The method as in claim 4, wherein the hard segments are polyamides chosen from the group consisting of the combination of C_6 or higher carboxylic acids and C_6 or higher organic diamines and C_6 or higher, aliphatic ω-amino-α-acids.

10. The method as in claim 1, wherein the second pressure is within the range of 1-10 psi.

11. A balloon for a medical device made by the method as in claim 1.

12. A balloon as in claim 11 having an operating pressure to which the balloon may be safely inflated without bursting of at least 12 atmospheres, a diameter at 3 atmospheres of from about 1.5 to about 3.0 mm, a generally linear diameter growth rate over the range of 3-12 atmospheres, and a diameter growth of at least 0.25 mm over the range of 3-12 atm.

13. A balloon as in claim 12 wherein said diameter growth is at least 0.5 mm.

14. A balloon as in claim 11 having an operating pressure to which the balloon may be safely inflated without bursting of at least 12 atmospheres, a diameter at 3 atmospheres of from about 3.25 to about 6.0 mm, a generally linear diameter growth rate over the range of 3-12 atmospheres, and a diameter growth of at least 1.0 mm over the range of 3-12 atm.

15. A balloon as in claim 11 having an operating pressure to which the balloon may be safely inflated without bursting of at least 10 atmospheres, a diameter at 3 atmospheres of from about 6 to about 12 mm, a generally linear diameter growth rate over the range of 3-10 atmospheres, and a diameter growth of at least 2 mm over the range of 3-10 atm.

16. A balloon as in claim 11 having an operating pressure to which the balloon may be safely inflated without bursting of at least 9 atmospheres, a diameter at 3 atmospheres of from about 12 to about 30 mm, a generally linear diameter growth rate over the range of 3-9 atmospheres, and a diameter growth of at least 3 mm over the range of 3-9 atm.

17. A balloon as in claim 16 wherein said diameter growth is at least 4 mm.

18. A balloon for a medical device characterized by an operating pressure to which the balloon may be safely inflated without bursting of at least 12 atmospheres, a diameter at 3 atmospheres of from about 1.5 to about 3.0 mm, a generally linear diameter growth rate over the range of 3-12 atmospheres, and a diameter growth of at least 0.5 mm over the range of 3-12 atm.

19. A balloon for a medical device characterized by an operating pressure to which the balloon may be safely inflated without bursting of at least 12 atmospheres, a diameter at 3 atmospheres of from about 3.0 to about 6.0 mm, a generally linear diameter growth rate over the range of 3-12 atmospheres, and a diameter growth of at least 1.0 mm over the range of 3-12 atm.

20. A balloon for a medical device characterized by an operating pressure to which the balloon may be safely inflated without bursting of at least 10 atmospheres, a diameter at 3 atmospheres of from about 6 to about 12 mm, a generally linear diameter growth rate over the range of 3-10 atmospheres, and a diameter growth of at least 2 mm over the range of 3-10 atm.

21. A balloon for a medical device characterized by an operating pressure to which the balloon may be safely inflated without bursting of at least 9 atmospheres, a diameter at 3 atmospheres of from about 12 to about 30 mm, a generally linear diameter growth rate over the range of 3-9 atmospheres, and a diameter growth of at least 3 mm over the range of 3-9 atm.

22. A balloon as in claim 21 wherein said diameter growth is at least 4 mm.

23. A balloon for a medical device characterized by a burst pressure of at least 9 atmospheres, a diameter at 3 atmospheres of about 2 mm or more, and an average compliance over the range of from 3 atmospheres to burst of at least 3% per atmosphere.

24. A balloon as in claim 23 wherein said average compliance over the range of from 3 atmospheres to burst is at least 4% per atmosphere.

25. A balloon as in claim 23 made from thermoplastic polymer material which is a block copolymer, a thermoplastic elastomer, a polymer blend, a random copolymer of rigid and flexible monomers, polyurethanes which have rigid and flexible portions, polyketones, polysulfides or a polyamide homopolymer or copolymer.

26. A balloon as in claim 23 formed from at least two concentric layers of different thermoplastic polymers.

27. A balloon as in claim 23 wherein said diameter at 3 atmospheres is about 5 mm or more.

28 A balloon as in claim 23 wherein said diameter at 3 atmospheres is about 12 mm or more.

29. A method of forming a balloon for a medical device comprising:

radially expanding tubing of thermoplastic polymer material under elevated blowing pressure greater than 50 psi at an elevated blowing temperature to form the balloon to have a first diameter at 3 atm inflation pressure,

annealing the formed balloon at an elevated annealing temperature less than or equal to the blowing temperature, and at an annealing pressure which in the range of 0-20 psi, for a time sufficient to shrink the formed balloon to have a second diameter at 3 atm inflation pressure which is less than 90% of the first

diameter, and then

pressurizing the balloon in a fixed diameter form, said fixed diameter being greater than said second diameter but no more than 90% of said first diameter, at a pressure above the annealing pressure but no more than 50 psi and a temperature not less than said annealing temperature and not greater than said blowing temperature for a time to provide the balloon with a final diameter at 3 atm inflation pressure which is greater than said second diameter but not more than 90% of said first diameter.

30. A method as in claim 29 wherein said final diameter is 85% or less of said first diameter.

31. A method as in claim 29 wherein said final diameter is 65-75% of said first diameter.

32. A method as in claim 29 wherein the thermoplastic polymer material is a block copolymer, a thermoplastic elastomer, a polymer blend, a random copolymer of rigid and flexible monomers, polyurethanes which have rigid and flexible portions, polyketones, polysulfides or a polyamide homopolymer or copolymer.

33. In a method of treating a gastrointestinal lesion by inserting a catheter having a balloon thereon into the gastrointestinal tract, positioning the balloon at the lesion, inflating the balloon to accomplish treatment of the lesion, deflating the balloon and then withdrawing the catheter, the improvement wherein the balloon is a balloon as in claim 23.

34. A method as in claim 32 wherein the catheter is inserted into the gastrointestinal tract, and withdrawn therefrom, through an endoscope.